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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,546	02/16/2001	Sonya Franklin	875.037US1	5198

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/12/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,546

Applicant(s)

FRANKLIN, SONYA

Examiner

Charles L. Patterson, Jr.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/15/01, 1/29/02, 5/20/02 & 7/22/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3, 19-26 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-18, 20 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

Applicant's election with traverse of Group I, claims 1-2, 4-18 and 27-29 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the inventions are so closely related within the context of the disclosure that they cannot properly be considered independent and distinct within the meaning of 35 USC § 121. This is not found persuasive because the claims of the other groups are directed to structurally different embodiments and they are therefore independent and patentably distinct. Two proteins that have different amino acid sequences are structurally different from each other. The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 19-26 and 30-33 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

The disclosure is objected to because of the following informalities:

On page 8, lines 20-23 and 27-28, colors are mentioned. The figures filed 10/15/01 do not have colors.

In the description of Figure 2 (amended 10/15/01) "panel A", "panel B", "contact with an o in panel A" and "a * for representative P3" are recited.

However none of these recitation are seen in Figure 2.

In the paragraph spanning pages 9-10 "Figures 7A-B" are mentioned.

There is no separation of Figure 7 into part A and B.

Appropriate correction is required.

Claims 1 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1652

Claim 1 is grammatically incorrect in the recitation of "which is hydrolytic or redox active". Hydrolytic is an adjective and the adverb "hydrolytically" is required here.

Claim 8 is indefinite in the recitation of "A-DNA, B-DNA, or Z-DNA".

Abbreviations should be avoided in patent claims and in addition it is not known what these abbreviations stand for.

Claim 9 is indefinite in the recitation of "engrailed". It is not known what is meant by this term. If applicant can show where it is defined in the specification or in the prior art, this rejection would be overcome.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-18 and 27-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. Claim 27 is drawn to a method of use of the synthetic peptide of claim 1 to cleave a nucleic acid. As discussed *infra*, the specification does not appear to show this cleavage. Therefore it is maintained that the invention does not have a specific utility, absent convincing proof to the contrary.

Claims 1-2, 4-18 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specifi-

Art Unit: 1652

cation in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a combination written description and enablement rejection.

To start with, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Secondly, it is stated on page 55, last paragraph, that "synthetic metallopeptide catalyzes BNPP hydrolysis with rate constants on the order of $k=10^{-6} \text{ sec}^{-1}$ (Table 1)". Looking at Table 1 there is no "k" seen but "Rates (K_{obs}) ($\text{s}^{-1} \times 10^7$)" is seen in the last column. The values in this column vary from "11.3", which is apparently 113×10^6 to "212.0", which is apparently 2120×10^6 . This does not appear to be on the order of 10^{-6} sec^{-1} , as stated. Also in Table 1 the meaning of the first column is not understood. "10/10", "25/25" and "50/50" are in this column with different values in the other columns corresponding to these lines. All three of these concentration values are equal to 1, and this is not understood. Does this perhaps indicate that there is less Eu bound to the peptide? This is not clear from the specification. Also, the meaning of the fourth column is not understood and the difference with column 3 and this column is not understood. The only difference appears to be a subscript "2" in the fourth column, and the meaning of this subscript is apparently not addressed. The cleavage of BNPP is not the cleavage of a nucleic acid. Also, it appears that if the specification is shown to be enabled for anything, it should only be enabled for Eu/P3, Eu/P4a and Eu/EuP5L.

Art Unit: 1652

In the paragraph spanning page 50-51, a substitution of "A₄₃ → R₍₁₉₎", and "Q₄₄ → E₍₂₀₎" is mentioned. It is entirely unclear what is meant by this and to what residues the recitation is referring. There are 33 residues in SEQ ID NO:2, to which the instant recitations are referring and on page 50, line 27 it is stated that "P3 comprises... (T₂₇-L₃₄ and E₄₂-K₅₇)". This is 24 residues, but it is not clear to what sequence these residue numbers refer. In addition it is not understood how residues at one position, e.g. A at position 43, can be substituted for R at position (19). Also it is not clear what is meant to be indicated by the parentheses.

In the first paragraph on page 56, it is stated that Figure 8 shows that EuP3 catalyzes the cleavage of supercoiled, double-stranded DNA. Figure 8 appears to show that the level of "open circular" and "supercoiled" in each lane of lanes 10-15 are approximately the same. It is not understood how this figure shows that EuP3 catalyzes the cleavage of supercoiled, double-stranded DNA.

Claim 1 is drawn to a synthetic peptide with a DNA binding domain and a metal binding domain, with these two domains being the same. Apparently nowhere in the specification is it taught that these two domains are the same. What is apparently taught is that the peptides disclosed in the specification both bind a metal and possibly cleave a nucleic acid. It is not shown that the peptide "specifically binds a nucleic acid". Indeed, there is not shown to be anything "specific" for the nucleic acid cleavage, absent convincing proof to the contrary. In claim 2 "(SEQ ID NO:3), or a catalytically active portion thereof". Apparently there is no teaching in the specification as to what portion of SEQ ID NO:3 is catalytically active, and therefore the ordinary artisan would not be taught how to make the invention.


Art Unit: 1652

For the reasons discussed *supra*, it is maintained that one of ordinary skill in the art would not know how to make and/or use the invention. It is also maintained that this ordinary artisan would have had no assurance that the applicant had possession of the invention at the time of filing of the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
September 10, 2002